

Remarks

Claims 1-37 are presented for the Examiner's review and consideration. In this response, claims 31-37 have been added. Applicant believes the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

Interview

An Applicant Initiated Telephonic Interview with the Examiner was conducted on April 10, 2007. In accordance with MPEP §713.04, the substance of the interview was as follows:

A) No exhibits were shown or demonstrations conducted.

B) Claims 1, 13 and 19 were discussed.

C) Prior art reference Masini (6,500,179) was discussed.

D) It was agreed that Masini was not directed to a cutting block positioned on a side surface of the femur, and that Masini required Intra and Extramedullary alignment means, particularly with respect to the initial resection of the distal end of the femur, requiring IM means, and EM means 120, 124, 160. Accordingly, it was agreed that the reference was overcome. It was further agreed that the next Office Action would not be Final since no claim amendments were necessary in order to overcome the rejection.

E) Arguments were substantially as described for item "D", above.

F) No other pertinent matters were discussed with respect to this application. Other applications were discussed during the interview, the substance of which will be detailed in responses in the respective applications.

G) Results were as described in "D", above.

H) The interview was not conducted by email.

35 U.S.C. §102(e) Rejections

Claims 1-30 were rejected under 35 U.S.C. §102(e) as being anticipated by Masini (6,500,179) ("Masini"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

The rejection states that Masini shows a guide having a body configured and dimensioned for attachment to a side surface of an end portion of a bone 130. Applicant respectfully submits that cited reference 130, shown in Fig. 1, refers to the whole bone, generally. In the specification, and in all of the figures of Masini, the guide is shown and described as being attached to the end of the bone only. Accordingly, this element of the claimed invention is not met by the disclosure of Masini.

Further, the rejection states that Masini shows at least one guide surface (106,108,110,112) extending from one side of the guide member to an opposite side of the guide member. However, in the specification and in all of the figures of Masini, the guide slots do not extend from one side of the guide to the other; rather none of the guide slots extend through the center portion of the device. Accordingly, this element of the claimed invention is also not met by the disclosure of Masini.

Masini discloses a device incorporating a plurality of cutting guides, wherein at least one of the guides is used to resect or otherwise modify a bone to receive a prosthetic element... (Col. 1, lns. 50-52). ...the guides take the form of parallel, spaced-apart slots extending through at least a portion of the body... (Col. 2, lns. 3-4). ...With reference to fig. 1 of Masini, the device 102 optionally further includes a posterior gauge 120 coupled to a member 122, and an anterior gauge 124 coupled to a member 126. (Col. 3, lns. 17-19). With reference to fig. 2 of Masini, the members 122 and 126 preferably interlock within the body of the block 104, with a manually operated fastener 128 being used to compress the gauges while compressively urged against respective protrusions of a bone 130. (Id).

With reference to fig. 3 of Masini, ...the guide block preferably features a smooth, planar backside 330, enabling the device to be positioned against a previously prepared surface such as a resected distal surface. (Col. 3, lns. 49-51). To assist in positioning, subtle adjustments may be achieved by moving the guide body with a fine control knob 140 which, as shown in fig. 2 of Masini, couples to a rod 242 and toothed element 244. (Col. 3, lns. 57-60). The element 244, in turn, interacts with teeth 246 to move the entire block [up--?] and down relative to the bone when held in place by gauges 120 and 124 upon being tightened using fastener 128. (Id). Readouts 150 and 152 may be provided for a visual indication of element size selection, and/or one or more additional “feeler gauges” such as element 160 may be used to make contact with an appropriate portion of the bone indicative of a particular implant size. (Col. 3, ln.67 – Col. 4, ln. 4).

Thus, Masini does not disclose or suggest a guide member free of extramedullary or intramedullary alignment means. Rather, Masini discloses anterior and posterior gauges extending from the block and interlocking within the block, operative with a fine control knob and gear. There is not suggested other means by which the block is positioned. Moreover, the block of Masini is positioned against a flat distal end of the bone, which in the prior art, requires an intramedullary device for its creation.

Additionally, as discussed above, Masini does not disclose or suggest a guide member positioned on a side surface of an end portion of a bone, nor does Masini disclose or suggest a guide surface extending from one side of the guide member to an opposite side of the guide member.

In contrast, the present invention relates to a new and improved method of performing surgery, and instruments, implants, and other surgical implements that can be used in surgery. (Background). Regardless of the type of surgery to be performed, a limited incision may advantageously be utilized. (Id). The incision 114 is movable relative to the distal end portion 124 of the femur 126 to maximize exposure of the femur through the limited length of the incision. (¶[0174]). ...the minimally invasive surgical instruments, implants, systems, and methods disclosed herein represent a significant deviation from those used in open surgical procedures... (¶[0714]).

Although any one of many known surgical procedures may be undertaken through the limited incision, down sized instrumentation for use in the making of cuts in a femur and/or tibia may be moved through or part way through the incision. (§[0013]) The down sized instrumentation may be smaller than implants to be positioned in the knee portion of the patient. (Id).

With reference to Fig. 54 of the present invention ...a femoral cutting guide 800 is illustrated as being mounted on a lateral surface 802 of the femur 126. (§[0494]). However, the femoral cutting guide 800 could be mounted on the medial surface of the femur 126 if desired. (Id).

It is contemplated that the down sized instrumentation may have cutting tool guide surfaces of reduced length. (§[0014]). The length of the cutting tool guide surfaces may be less than the length of a cut to be made on a bone. (Id). A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool. (Id).

As such, the present invention provides a means for cutting bone, where the guide member is free of extramedullary or intramedullary members. As noted above, Masini fails to disclose a guide member free of extra or intramedullary members, a guide used on a side surface of a bone, or a guide with a surface extending from one side of the guide to an opposite side.

Claim 1 recites, *inter alia*, A method of performing surgery on a patient's knee including a femur and a tibia, the method comprising the steps of: making an incision in a knee portion of a leg of the patient; positioning a cutting guide through the incision and on a side surface of a distal end portion of the femur; moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; cutting the femur by moving the cutting tool along the guide surface, wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod.

Claim 13 recites, *inter alia*, a total knee replacement cutting guide for forming a cut surface on a bone in preparation to receive a total joint replacement component comprising: a guide member having a body configured and dimensioned for attachment to a side surface of an end portion of the bone free of an extramedullary or intramedullary alignment rod; and at least one

guide surface extending from one side of the guide member to an opposite side of the guide member, the at least one guide surface configured and dimensioned for engagement with a cutting tool to thereby direct the cutting tool in making only a portion of the cut surface.

Claim 19 recites, *inter alia*, a method of performing surgery on a joint in a patient including a first bone and a second bone, the method comprising the steps of: making an incision proximal to the joint in the patient; positioning a cutting guide through the incision and on a side surface of an end portion of the first bone; moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; cutting the first bone by moving the cutting tool along the guide surface, wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod.

Accordingly, applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Masini. As claims 2-12 depend from claim 1; claims 14-18 depend from claim 13; and claims 20-29 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Masini for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 102 rejection.

Applicant(s): P. Bonutti
Application No.: 10/722,102
Examiner: P. Philogene

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$350 is believed to be due for 7 additional dependent claims. A credit card payment form is being submitted herewith. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul Bianco", with a stylized flourish extending from the end.

Paul Bianco, Reg. #43,500

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